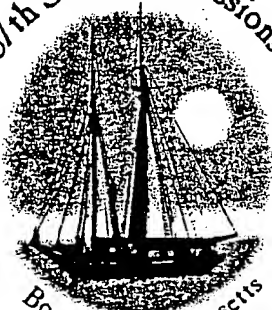


diabetes

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57th Scientific Sessions



Boston, Massachusetts
June 21-24, 1997

ABSTRACT BOOK

57th Annual Meeting and Scientific Sessions

Saturday, June 21 — Tuesday, June 24, 1997

Hynes Convention Center
Boston, Massachusetts

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Pramlintide, an Analog of Human Amylin Improves Glycemic Control in Patients with Type II Diabetes Requiring Insulin.

ROBERT THOMPSON*¹, LEEANNE PEARSON*¹, STEVEN SCHOENFELD*¹, ORVILLE KOLTERMAN*¹. *San Diego, CA*

The effects of 4 weeks of subcutaneous administration of pramlintide, (Pr) an analog of human amylin, on glycemic control in 203 patients with Type II diabetes mellitus requiring insulin were examined in a randomized, double-blind, placebo-controlled, parallel-group trial. Statistically significant reductions in serum fructosamine concentration were observed in the Pr 30 μ g QID group (17.5 ± 4.9 μ mol/L), the Pr 60 μ g TID group (24.1 ± 4.9 μ mol/L) and the Pr 60 μ g QID group (22.6 ± 4.1 μ mol/L) compared to placebo (PBO) (3.5 ± 3.8 μ mol/L). There also were statistically significant shifts in the proportion of patients with an abnormal serum fructosamine concentration at baseline that normalized at Week 4 within the Pr 60 μ g TID group (28%) and the Pr 60 μ g QID group (31%) compared to PBO (10%). Consistent with the reduction in fructosamine, there were also statistically significant reductions in HbA_{1c} in the Pr 30 μ g QID group ($0.53 \pm 0.07\%$), the Pr 60 μ g TID group ($0.58 \pm 0.07\%$) and the Pr 60 μ g QID group ($0.51 \pm 0.08\%$) compared to placebo ($0.27 \pm 0.08\%$). Based on RBC lifespan, and assuming stable glycemic control, these reductions in HbA_{1c} in the Pr groups should increase over the following 2-3 months. The reductions in fructosamine and HbA_{1c} were accompanied by a statistically significant reduction in fasting total and LDL cholesterol. In contrast to treatment with insulin alone, there were trends towards decreased body weight in the Pr 60 μ g TID and 60 μ g QID groups. Furthermore, the incidence of hypoglycemia was no greater in any Pr group than in placebo. In conclusion, measurement of similar changes in both serum fructosamine concentration and HbA_{1c} suggests that pramlintide therapy for 28 days improves glycemic control in patients with Type II diabetes mellitus requiring insulin.

SEP - 7 2004

PTO/SB/17 (10-02)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL

for FY 2003

Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

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Complete if Known

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First Named Inventor

DLIFT

Examiner Name

DEVI SARVAMANGALAJN

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METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number
Deposit Account Name

50-1273

BROBECK, PHLEGGER & HARKEN

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☐ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 740	2001 370	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 510	2003 255	Plant filing fee	
1004 740	2004 370	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 400	2252 200	Extension for reply within second month	
1253 920	2253 460	Extension for reply within third month	460.00
1254 1,440	2254 720	Extension for reply within fourth month	
1255 1,960	2255 980	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,280	2453 640	Petition to revive - unintentional	
1501 1,280	2501 640	Utility issue fee (or reissue)	
1502 460	2502 230	Design issue fee	
1503 620	2503 310	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 740	2809 370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	
1801 740	2801 370	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

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Date

12/5/2002

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